

In re Patent Application of: AOKI, et al.,))
Serial Number: 09/550,371 Filed: April 14, 2000	Examiner: C.M. KAM Group Art Unit: 1646
For: METHOD FOR TREATING PAIN BY) PERIPHERAL ADMINISTRATION OF A NEUROTOXIN)	Irvine, California

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant herewith submits a one- page form PTO 1449 for consideration by the Examiner, consistent with the provisions of 37 CFR § 1.97 and 1.98. By submitting this Information Disclosure Statement, Applicant makes no admission that any item listed thereupon is material to the patentablility of the invention claimed in the above-entitled patent application. Further, Applicant makes no assertion hereby that a search was conducted, or if conducted, that any search was thorough.

Applicant respectfully requests that the Examiner indicate consideration of the cited reference by returning a copy of the attached form PTO-1449 with the Examiner's initials or other appropriate marks.

If any fee is required please charge Deposit Account No. 01-0885 the appropriate amount and please consider this communication a petition requesting

consideration of this supplemental IDS.

Date: September 13, 2001

Allergan, Inc. 2525 Dupont Drive, T2-TH

Irvine, CA 92612 Tel: 714 246 4026 Fax: 714-246-4249 Respectfully submitted,

Stephen Donovan

Registration Number 33,433

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Supplemental Information Disclosure Statement is being deposited with the United States Postal Service on **September 13, 2001** in an envelope as "Express Mail Post Office To Addressee" mailing label number EL385557033US with sufficient postage for Express Mail addressed to Assistant Commissioner for Patents, Washington, D.C., 20231.

Susan Bartholomew

Name of person mailing paper

Signature of person mailing paper

Date: September 13, 2001

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

Sheet	1	of	1

LIST OF ART CITED BY APPLICANT

BIST OF THE	CIALD DI III I DI CIA I
ATTY. DOCKET: 17328	SERIAL NO.: 09/550,371
APPLICANT: AOKI, ET AL.,	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE: April 14, 2000	GROUP:

UNITED STATES PATENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,113,915	9/5/00	AOKI	424	236	·

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (yes/n)
0						
						·

OTHER ART

EXAMINER_				 		 DAT	E C	ONSIE	EREI			
_	 	 	 		_	 	_			 	_	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Aoki et al.) E:	xaminer:
U.S. Serial No.:	09/550,371) A	rt Unit:
Filed:	April 14, 2000)	
For:	METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN))))	

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-referenced patent application one copy the document listed on the attached Form PTO-1449, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56.

While this document may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge Deposit Account Number 01-0885 for any fees or charges associated with the filing of this paper and any of the attached pages and to refund any overpayment to the same deposit account.

Respectfully submitted,

Date: November 28 2000

Telephone: 714 246 4026

Fax: 714 246 4249

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 Stepher Donovan

Registration Number 33,433

U.S. Serial Number: 05,550,371 Filed: April 14, 2000

Docket No: 17328 (AP)

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Supplementary Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Maria Zirbes
Name of Person Mailing

Signature of Person Maiking

Date: 11.28.00

U.S. Departm	ent of Cor	nmerce, Patent and T	rademark Offi	ce PTO form 1449	Atty Docket	No.	Serial No.	
				17328 (AP)	09/550,371			
INFO	RMATIO	N DISCLOSURE ST	ATEMENT B	Y APPLICANT	Applicant(s)	Aoki et al.		
		(Use several sheets	if necessary)	· · · · · · · · · · · · · · · · · · ·				
					Filing Date	October 4, 2000	Group	
	×							
·			U.S.	Patent Documents			! ;/////////	
*Examiner	T	Document					Filing Da	
Initial		Number	Date	Name	Class	Subclass	If Appropr	riate
	AA -	6,063,768	5/26/00	First		·		
	AB			*				
	AC							
	AD			1		<u>:</u>		
	AE							
	AF							
<u> </u>	AG							
	AH							
	AI						•	
	AJ					1		
	AK			 				
	. Aix	<u></u>	Foreig	n Patent Documents	_i	11	•	
	····		TOTOLE	in I atom Documents	· · · · · · · · · · · · · · · · · · ·		Trans	slation
		<u> </u>	Doto	Country	Class	Subclass	Yes	No
		Document	Date	Country	Ciass	Succiass	165	140
	AL	ļ				,	 :	-
	AM			<u> </u>		<u> </u>		
	AN	•						
	AO							
¥	AP							
		OTHER A	RT (Including	Author, Title, Date, Pe	ertinent Pages,	Etc.)		
	AQ							
	AR							
	1,77	*						
	AS	1						-
	AS							
		<u> </u>	Date Conside			·		
Examiner	D 7	· · · · · · · · · · · · · · · · · · ·				ADED 600. Dans	ling through	
*EXAMINE	K; INITIAL t in confor	in reference considere	zu, waeuter or dered. Include	not citation is in confo	h your commu	nication to application	ant.	•
J								

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Date: December 3, 2001

AOKI, et al.

Examiner: Chih-Min-Kam

Serial Number: 09/550,371

Group Art Unit: 1653

Filed: April 14, 2000

For ME

METHODS FOR TREATING PAIN

BY PERIPHERAL

ADMINISTRATION OF A

NEUROTOXIN

EL385558997US

Irvine, California

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Applicant provides with regard to the above-referenced patent application a copy of the document listed on the attached 1-page Supplementary Information Disclosure Citation (Form PTO-1449), which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56.

While this document may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement. These documents were disclosed in an International Search Report in the foreign counterpart of the above-identified application, and the International Search Report was received less than three (3) months ago.

ATTORNEY DOCKET 17328(BOT)

The Commissioner is hereby authorized to charge any fees associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Date: December 3, 2001

Respectfully submitted,

Allergan, Inc.

2525 Dupont Drive, T2-7H

Irvine, CA 92612 Tel: 714 246 4026 Fax: 714-246-4249 Sternen Donovan

Redistration Number 33,433

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Supplemental Information Disclosure Statement is being deposited with the United States Postal Service on **December 3, 2001** in an envelope as "Express Mail Post Office To Addressee" mailing label number EL385558997US with sufficient postage for Express Mail addressed to Assistant Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

Susan Bartholomew

Name of person mailing paper

Date: December 3, 2001

Signature of person mailing paper

SUPPLEMENTAL LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17328 (BOT)	SERIAL NO.: 09/550,371
APPLICANT: AOKI, et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATIONOF A NEUROTOXIN
FILING DATE: APRIL 14, 2000	GROUP: 1653

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,113,915	9/5/00	AOKI	424		
	AB						
	AC						
·	AD		•				
	AE						

FOREIGN PATENT DOCUMENTS

			DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
Ì	B	A	WO 97/34624	9/25/97	PCT			
ľ	B	В	WO 96/33273	10/24/96	PCT			
Ì	В	c	WO 95/30431	11/16/95	PCT			

OTHER ART

		(Including Author, 11tle, Date, Pertinent Pages, etc.)
	CA	Guyer, B., Mechanism of botulinum toxin in the relief of chronic pain, Current Review of Pain, 1999, 3:427-431, XP-001031379
	CB	Carruthers, A., et al., Improvement of tension-type headache when treating wrinkles with botulinum toxin A injections, Headache, Oct. 1999:39:662-665, XP-001031356
	CC	Diaz, J., et al., Management of post-thoracotomy pseudoangina and myofascial pain with botulinum toxin, Anesthesiology, V 91, No. 3, Sep 1999, pp. 877-879, XP-001031347
	CD	Silberstein, S., et al., Botulinum toxin type A as a migraine preventive treatment, Headache 2000:40:445-450, XP-002182692
	CE	Gobel, H., et al., Evidence-based medicine: botulinum toxin A in migraine and tension-type headache, Journal of Neurology, 2001 248 Supp 1: I/34-I/38, XP-002182693
•		

EXAMINER	DATE CONSIDERED
AND	bestern a construction to the conference of the APED 600. Down line through sitation if not

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

I H

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	of: DONOVAN, Stephen) Examiner:
U.S. Serial No.:	09/550,371) Art Unit: 1646
Filed:	April 14, 2000)
For:	METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A	
•	NEUROTOXIN) Irvine, California

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant provides with regard to the above-referenced patent application one copy of each of the eight documents listed on the attached Form PTO-1449, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. Please note that the Li, Schantz and Zhou articles were originally cited by applicant at the time the application was filed; however; copies of those references were not available at that time and are therefore being submitted herein.

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that any such document is prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees associated with this communication, or credit any overpayment, to Deposit Account No. 01-0885.

Respectfully submitted,

Date: August 9, 2000

Stepher/Donovan

Registration Number 33,433

Docket No. 17328 (AP)

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 Telephone: 714 246 4026

Fax: 714 246 4249

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this Supplementary Information Disclosure Statement and any additional documents set forth as being enclosed herein are being deposited with the United States Postal Service on the date shown below, with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231.

Mary Stickle
Name of Person Mailing

Date: August 10, 2000

Signature of Person Mailing

Sheet	_1_	of	_1_
-------	-----	----	-----

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.: 09/550,371			
APPLICANT:	A ki et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN			
FILING DATE:	04/14/2000	GROUP: 1646			

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	<u> </u>	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,063,768	5/16/00	FIRST			
	AB			,			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n)
BA				_		
BB						

OTHER ART

	CA	1
	·	News 2000;31(3):16.
	CB	First, E. et al.; Painful Cervical Dystonia: Response to Treatment with Botulinum Toxin;
		Mov Disord 1998;13(Suppl2):100.
	CC	Guyer, Barry M.; Mechanism of Botulinum Toxin in the Relief of Chronic Pain; Curr Rev
		Pain 1999;3(6):427-431.
· ·	CD	Li, Yan, et al.; A Single Mutation in the Recombinant Light Chain of Tetanus Toxin Abolishes
·		Its Proteolytic Activity and Removes the Toxicity Seen after Reconstitution with Native Heavy
		Chain; Biochemistry 1994, 33, 7014-7020.
	CE	Schantz, Edward J., et al.; Properties and Use of Botulinum Toxin and Other Microbial
,		Neurotoxins in Medicine; Microbiological Reviews Mar. 1992, pp. 80-99, Vol. 56, No. 1.
	CF	Tarsy, Daniel, et al.; Painful Cervical Dystonia: Clinical Features and Response to
,		Treatment With Botulinum Toxin; Mov Disord 1999;14(6):1043-1045.
	CG	Zhou, Liqing, et al.; Expression and Purification of the Light Chain of Botulinum Neurotoxin
		A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after
		Reconstitution with the Heavy Chain; Biochemistry 1995, 34, 15175-15181.
	СН	

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered,	whether or not citation is in conformance with MPEP 609; Draw line through citation if not in
conformance and not considered. Include conv	of this form with next communication to applicant.

ATTORNEY DOCKET 17328(AP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	AOKI, et al.)	Examiner:
U.S. Serial No.:	Pending)).	Art Unit:
Filed:	(Herewith))	
	R TREATING PAIN BY PERIPHERAL TION OF A NEUROTOXIN))	Irvine, California

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate the documents as may be appropriate. Applicant requests that each of these documents be made of record in the above-identified application.

Respectfully submitted,

Date: April 14, 2000

Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612

Telephone: 714 246 4026

Fax: 714 246 4249

Registration Number 33,433

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

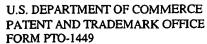
I hereby certify that this Transmittal Letter and the additional documents set forth above as being enclosed herein are being deposited with the United States Postal Service on April 14, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL079092522US, addressed to BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, DC 20231.

STEPHEN DONOVAN

Name of person mailing paper

Signature of person mailing paper

Date: April 14, 2000







ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	5,714,468	2/3/98	BINDER	:		· · · · · ·
	AB	5,766,605	6/16/98	SANDERS ET AL.			
	AC	5,989,545	11/23/99	FOSTER ET AL.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
BA	94/15629	7/21/94	PCT			
BB	96/33273	10/24/96	PCT			
BC	98/07864	2/26/98	PCT			,
BD	99/17806	4/15/99	PCT			

OTHER ART

		Barwood, Shane, et al.; Analgesic Effects of Botulinum Toxin A: A Randomized, Placebo- Controlled Clinical Trial; Developmental Medicine & Child Neurology, 2000; 42:116-121
	СВ	Bigalke, H., et al.; Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission
	CC	in Mouse Spinal Cord Neurons in Culture; Brain Research, 360 (1985); 318-324. Bigalke, H., et al.; Tetanus Toxin and Botulinum A. Toxin Inhibit Release and Uptake of
		Various Transmitters, as Studied with Particulate Preparations from Rat Brain and Spinal Cord; Naunyn-Schmiedeberg's Arch. Pharmacol (1981); 316:244-251.
C		Cheshire, et al.; Botulinum Toxin in the Treatment of Myofascial Pain Syndrome; Pain, 1994; 59(1):65-9.
	[.	DiStefano, P. S., et al.; Receptor Mediated Retrograde Axonal Transport of Neurotrophic Factors is Increased After Peripheral Nerve Injury; Progress in Brain Research (1994); Vol. 103; Chapter 4; 35-42.

EXAMINER	DATE CONSIDERED
ATTICAL COLUMN TO A STATE OF THE STATE OF TH	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

CF	Dixon, W. J.; Efficient Analysis of Experimental Observations; Ann. Rev. Pharmacol.
	<u>Toxicol.</u> (1980); 20:441-462.
CG	Dubuisson, D., et al.; The Formalin Test: A Quantitative Study of the Analgesic Effects of Morphine, Meperidine, and Brain Stem Stimulation in Rats and Cats; Pain (1977); 4:161-174.
СН	Duc, C., et al.; Ultrastructural Localization of SNAP-25 Within the Rat Spinal Cord and Peripheral Nervous System; The Journal of Comparative Neurology (1995); 356:152-163.
CI	Fauci, A.S., et al. (Editors); <u>Harrison's Principles of Internal Medicine</u> , 14 th Edition (1998); McGraw-Hill; 2064-2065.
CJ	Garner, C.G., et al.; Time Course of Distant Effects of Local Injections of Botulinum Toxin; Movement Disorders; Vol. 8, No. 1; 1993.
СК	Habermann, E.; Inhibition by Tetanus and Botulinum A Toxin of the Release of (³ H)noradrenaline and (³ H)GABA from Rat Brain Homogenate; Experientia 44 (1988); 224-226.
CL	Habermann, E.; I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord; Naunyn Schmiedeberg's Arch. Pharmacol.; 281, 47-56 (1974).
CM	Habermann, E., et al.; Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release from Cultured Mouse Brain; Journal of Neurochemistry; Vol. 51; No. 2 (1988); 522-527.
CN	Hagenah, R., et al.; Effects of Type A Botulinum Toxin on the Cholinergic Transmission at Spinal Renshaw Cells and on the Inhibitory Action at Ia Inhibitory Interneurones; Naunyn-Schmiedeberg's Arch. Pharmacol.; 299, 267-272 (1977).
СО	Halpern, J.L., et al.; Neurospecific Binding, Internalization, and Retrograde Axonal Transport; Date Unknown; pp. 221-241.
СР	Johnson, E., et al.; Biomedical Aspects of Botulinum Toxin; J. ToxicolToxin Reviews; Feb. 18, 1999; 18(1):1-15.
CQ	Jung, H. H., et al.; Expression of Neurotransmitter Genes in Rat Spinal Motoneurons After Chemodenervation with Botulinum Toxin; Neuroscience (1997); Vol. 78, No. 2; 469-479.

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

	CR	1 ====, == , == , = = , = ; =
		Spinal Nerve Ligation in the Rat; Pain, 50 (1992); 355-363.
	CS	Li et al.; Biochemistry; 33:7014-7020 (1994).
	CT	Mochida, S., et al.; Impairment of Syntaxin by Botulinum Neurotoxin C ₁ or Antibodies
·		Inhibits Acetylcholine Release but not Ca ²⁺ Channel Activity; Neuroscience (1995); Vol. 65; No. 3; 905-915.
	CU	Naumann, et al.; Botulinum Toxin Type A in the Treatment of Focal, Axillary and Palmar
]	Hyperhidrosis and Other Hyperhidrotic Conditions; European Journal of Neurology, 1999;
		Vol. 6(suppl4):S3-S10 and S111-S115.
	CV	Nelson, P.G., et al.; Mouse Spinal Cord in Cell Culture. IV. Modulation of Inhibitory
		Synaptic Function; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1178-1187.
	CW	Osen-Sand, A., et al.; Inhibition of Axonal Growth by SNAP-25 Antisense Oligonucleotides in
		vitro and in vivo; Nature; 29 July 1993; Vol. 364; 445-448.
	CX	Pearce, L. B., et al.; Pharmacologic Characterization of Botulinum Toxin for Basic Science
•		and Medicine; Toxicon (1997); Vol. 35, No. 9; 1373-1412.
	CY	Ragona, et al.; Management of Parotid Sialocele with Botulinum Toxin; Laryngoscope,
		109:August 1999; p. 1344-36
	CZ	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. I. Morphology and Intrinsic
i		Neuronal Electrophysiologic Properties; Journal of Neurophysiology; Vol. 40, No. 5; Sept.
		1977; 1132-1150.
	DA	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. II. Synaptic Activity and Circuit
		Behavior; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1151-1162.
	DB	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. III. Neuronal Chemosensitivity and
		its Relationship to Synaptic Activity; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977;
		1163-1177.
	DC	Rees, H., et al.; Do Dorsal Root Reflexes Augment Peripheral Inflammation?; Neuro Report;
		Vol. 5, No. 7; 21 March 1994; 821-824.
	DD	Sanchez-Prieto, J., et al.; Botulinum Toxin A Blocks Glutamate Exocytosis from Guinea-Pig
		Cerebral Cortical Synaptosomes; Eur. J. Biochem. (1987); 165:675-681.

EX	ΔM	${ m IIN}$	ER

DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.:
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP:

OTHER ART (Continued)

(Including Author, Title, Date, Pertinent Pages, etc.)

	DE	Shantz, E.J., et al.; Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine; Microbiol Rev.; 56:80-99 (1999).
	DF	Simpson, L.; Botulinum Toxin: Potent Poison, Potent Medicine; Hospital Practice; April 15,
		1999; 34(4):87-91.
	DG	Singh, B.R.; Critical Aspects of Bacterial Protein Toxins; Natural Toxins II (1996); Plenum
	1	Press, New York; pp. 63-84.
	DH	Tonra, J. R., et al.; Axotomy Upregulates the Anterograde Transport and Expression of
		Brain-Derived Neurotrophic Factor by Sensory Neurons; The Journal of Neuroscience; June
		1, 1998; 18(11):4374-4383.
	DI	Tsuda, M., et al.; In vivo Pathway of Thermal Hyperalgesia by Intrathecal Administration of
		lpha, eta-methylene ATP in Mouse Spinal Cord: Involvement of the Glutamate-NMDA Receptor
	<u>L</u>	System; Br. J. Pharmacol (1999); 127(2):449-456.
	DJ	Wiegand, H., et al.; The Action of Botulinum A Neurotoxin on the Inhibition by Antidromic
1		Stimulation of the Lumbar Monosynaptic Reflex; Naunyn-Schmiedeberg's Arch. Pharmacol.
		(1977); 298:235-238.
	DK	Wiegand, H., et al.; I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats After
		Intramuscular Injection; Nauyn-Schmiedeberg's Arch. Pharmacol.; 292, 161-165 (1976).
	DL	Williamson, L. C., et al.; Clostridial Neurotoxins and Substrate Proteolysis in Intact
		Neurons; The Journal of Biological Chemistry; Mar. 29, 1996; Vol. 271:13; 7694-7699.
	DM	Williamson, L. C., et al.; Differential Effects of Tetanus Toxin on Inhibitory and Excitatory
		Neurotransmitter Release from Mammalian Spinal Cord Cells in Culture; Journal of
		Neurochemistry; 1992; Vol. 59:6; 2148-2157.
	DN	Willis, W. D.; Pain; The Rat Nervous System; Second Edition; 1995; Academic Press, Inc.;
		pages 725-750.
	DO	Woolf, C. J., et al.; Neuropathic Pain: Aetiology, Symptoms, Mechanisms, and Management;
		The Lancet; June 5, 1999; Vol. 353; 1959-1964.
	DP	Yaksh, T. L., et al.; Chronic Catheterization of the Spinal Subarachnoid Space; Physiology &
		Behavior (1976); Vol. 17:1031-1036.
	DQ	Zhou et al., Biochemistry; 34:15175-15181 (1995).

CV	Aλ		\mathbf{r}
EX.	ΑЛ	ИШΝ	IER

DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Application/Control No. Applicant(s)/Patent Under Reexamination 09/550,371 AOKI ET AL. Notice of References Cited Examiner Art Unit Page 1 of 1 Chih-Min Kam 1653

U.S. PATENT DOCUMENTS

424/239.1

FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N	1				
C					
F					
C					
R					
s					
7					

NON-PATENT DOCUMENTS

$\overline{}$		NON-I ATEM DOCUMENTS
*	ļ	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	w	
	x	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

, 1		M (1		1,	09/550,371 Rock		Applicant(s)/Palant Under Rooxamination AOKI ET AL			
		Notic of R fero	ences Cite	~/ L.			Art Unit	1		
					01:1.44: 14			Page 1	of 1	
\vdash					Chih-Min Kam ENT DOCUMENTS		1653			
*		DOCUMENT NO.	DATE	0.0.174	NAME		SUBCLASS	POOLYBUL		
<u> </u>	+							APA	OTHER	
								9	0	
								0	-	
ㅁ	+		-		· · · · · · · · · · · · · · · · · · ·			0	0	
	D							0	0	
	E							0	0	
	F				-			0	0	
	G							0	0	
	Н							0	0	
	1	-			· · · · · · · · · · · · · · · · · · ·			0	0	
	J							0	0	
0	K							0	0	
0	l,	·						0	0	
0	M							0	0	
FOREIGN PATENT DOCUMENTS										
	territoria.			FOREIGN P	ATENT DOCUMENTS			Locum	NT	
*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	DOCUME SOURCE APS	NT OTHER	
• 0	2	DOGUMENT NO. WO 95/17904	DATE Jul. 1995				SUBCLASS 38/16	SOURCE		
				COUNTRY	NAME	CLASS		APS	OTHER	
0	-	WO 95/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER	
00	0	WO 95/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	APS	OTHER	
000	0 0	WO 95/17904	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER	
0000	0 0 0	WO 95/17904 WO 94/15629	Jul. 1995	COUNTRY	NAME Aoki et al.	CLASS A61K	38/16	SOURCE APS	OTHER	
0 0 0 0 0 0	0 P O R	WO 95/17904 WO 94/15629	Jul. 1995	US	NAME Aoki et al. Borodic et al.	CLASS A61K	38/16	SOURCE APS	OTHER	
0 0 0 0 0 0	O P O R S	WO 95/17904 WO 94/15629	Jul. 1995	US	NAME Aoki et al. Borodic et al.	CLASS A61K	38/16	SOURCE APS	OTHER	
0000000	O P O R S	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al.	CLASS A61K A61K	38/16	SOURCE APS D D D D D D D D D D D D D	OTHER S S T T T T T T T T T T T	
000000	O P O R S	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al.	CLASS A61K A61K	38/16	SOURCE APS	OTHER S S T T T T T T T T T T T	
	O P Q R S T	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al.	CLASS A61K A61K	38/16	BOURCE APS DOCUME SOURCE APS	OTHER S OTHER OTHER	
	O P Q R S T	WO 96/17904 WO 94/18629	Jul. 1995 Jul. 1994	US US NON-PAT	NAME Aoki et al. Borodic et al.	CLASS A61K A61K	38/16	BOURCE APS DOCUME SOURCE APS	OTHER OTHER OTHER	

^{*}A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)
**APS encompasses any electronic search i.e. text, image, and Commercial Databases.
U.S. Patent and Trademark Office
PTO-892 (Rev. 03-98)

Notice of References Cited